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RULE PROPOSALS

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
BOARD OF PHARMACY

40 N.J.R. 1072(a)

Jointly Proposed New Rules: N.J.A.C. 13:35-6.26 and 13:39-4.20

Click here to view Interested Persons Statement

Procedures for Physician Ordered or Government Sponsored Immunizations Performed by Pharmacists

Authorized By: State Board of Medical Examiners, William Roeder, Executive Director, and Board of Pharmacy, Joanne Boyer, Executive Director.

Authority: N.J.S.A. 45:14-48a(5) and *45:14-63*.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2008-49.
Submit comments by May 2, 2008 to:
William Roeder, Executive Director
Board of Medical Examiners
140 East Front Street, 2nd Floor
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and to:
Joanne Boyer, Executive Director
Board of Pharmacy
P.O. Box 45013
Newark, N.J. 07101

The joint proposal of the agencies follows:

Summary

The State Board of Medical Examiners and the Board of Pharmacy are jointly proposing new rules that will permit licensed pharmacists to immunize non-pediatric patients. The proposed new rules authorize pharmacists to administer vaccines pursuant to a physician's prescription that is patient specific, and in immunization programs that are not patient specific that are implemented pursuant to a supervising physician's standing order. The proposed new rules also authorize pharmacists to administer vaccinations in government sponsored programs that are also not patient specific. The Pharmacy Practice Act, at N.J.S.A. 45:14-48a(5) and *45:14-63*, authorizes the Boards to jointly promulgate regulations for pharmacist-administered immunizations. The Boards believe that permitting patients to receive vaccinations from appropriately trained pharmacists at pharmacy practice sites throughout the State may lead to an overall increase in the number of patients who will become immunized, which may lead to an overall reduction in healthcare costs for some New Jersey consumers.

The State Board of Medical Examiners proposed N.J.A.C. 13:35-6.26(a) and the Board of Pharmacy proposed N.J.A.C. 13:39-4.20(a) provide that a physician and a pharmacist may participate in a physician-pharmacist immunization program provided the pharmacist administers the vaccines pursuant to the physician's prescription (for patient specific immunizations) or standing order (for patient non-specific immunizations). The prescription or standing order will authorize the pharmacist's administration of the specific vaccine, as well as the pharmacist's administration of the emergency medications diphenhydramine and epinephrine in those instances where a patient has an adverse reaction to a particular vaccine. Proposed N.J.A.C. 13:39-4.20(a) also authorizes pharmacists to administer vaccinations in immunization programs sponsored by government agencies that are not patient specific as is authorized under the Pharmacy Practice Act at *N.J.S.A. 45:14-63(b)*.

Proposed N.J.A.C. 13:35-6.26(a) specifies that a physician may only participate in a physician-pharmacist immunization program with a pharmacist who has been approved by the Board of Pharmacy to perform immunizations. Under Board of Pharmacy proposed new rule N.J.A.C. 13:39-4.20(b), a pharmacist must be pre-approved by the Board of Pharmacy in order to be eligible to participate in immunization programs. In order to obtain Board approval, a pharmacist must have completed a formal course of study, approved by the Accreditation Council for Pharmacy Education, in Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007, which is incorporated in N.J.A.C. 13:39-4.20(b) by reference, as may be amended and supplemented. The current CDC guidelines can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf. The guidelines establish standards with respect to patient and vaccine preparation, vaccine selection and vaccine administration techniques. The course must also include instruction in the Occupational Health Safety Administration (OSHA) standard for bloodborne pathogens. This standard is set forth in OSHA regulations found at *29 C.F.R. §1910.1030*, and have been adopted as the standard for public employees under the New Jersey Public Employees Occupational Safety and Health (PEOSH) Act, pursuant to *N.J.S.A. 34:6A-25* et seq. This standard, which establishes requirements for dealing with occupational exposure to blood and other potentially infectious materials, is incorporated in N.J.A.C. 13:39-4.20(b) by reference as may be amended and supplemented.

An approved course must also provide pharmacists with instruction in the CDC Guideline for Infection Control in Health Care Personnel (1998). This CDC guideline, which is designed to reduce the transmission of infections among patients and health care professionals, is incorporated in N.J.A.C. 13:39-4.20(b) by reference, as may be amended and supplemented, and may be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/InfectControl98.pdf. The course must also include instruction in immunology, communicable or vaccine preventable disease epidemiology, vaccine characteristics and contraindications, as well as the immunization schedules established pursuant to "General Recommendations on Immunization" of the CDC Advisory Committee on Immunization Practices (December 1, 2006). These recommendations, which are incorporated by reference in N.J.A.C. 13:39-4.20(b), as may be amended and

supplemented, can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm. A pharmacist must also be currently certified in the American Heart Assoction Basic Life Support (BLS) or the Red Cross Adult Cardiac Pulmonary Resuscitation (CPR) protocol for health care providers, as well as currently certified in the use of a heart defibrillator.

Subsections (c) and (d) of proposed new rule N.J.A.C. 13:39-4.20 require a participating pharmacist to maintain documentation of his or her training at the pharmacy practice site, or in his or her possession if the immunizations are being conducted at a location other than the pharmacy practice sire. The documentation must be made available for inspection by the Board of Pharmacy upon request. Board of Pharmacy approval to provide immunizations must be renewed on a biennial basis. In order to be eligible for renewal, the pharmacist must present proof of current certification in the BLS or CPR protocol and use of a defibrillator, as well as completion of at least two hours of continuing education in immunizations.

Proposed N.J.A.C. 13:35-6.26(b) and 13:39-4.20(n) require that if a physician provides a pharmacist with a standing order to administer vaccines and related emergency medications, the physician must supervise the pharmacist's immunization activities. The supervising physician must formulate or approve the standing order, which must include compliance with CDC guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007. The CDC guidelines are also incorporated by reference, as may be amended and supplemented, in N.J.A.C. 13:35-6.26(b). The standing order must also include compliance with American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005), including the use of automated external defibrillators (AED). The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005) are incorporated by reference, as may be amended and supplemented, in N.J.A.C. 13:35-6.26(b) and N.J.A.C. 13:39-4.20(b), and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/vol112/24_suppl/.

The physician's standing order must also include procedures for reporting adverse events. The physician must annually review the standing order and the immunization services being provided to patients by the pharmacist under the order. In addition, the supervising physician must be located so as to be easily accessible to the pharmacy practice site or immunization location, and he or she must be readily available for consultation with the pharmacist through direct telecommunication. The pharmacist must provide the supervising physician with an annual status report on the immunization program.

Under proposed N.J.A.C. 13:39-4.20(e), a participating pharmacist must maintain a policies and procedures manual. The manual must specify that the pharmacist is to immediately notify emergency medical personnel and obtain assistance for any patient who experiences an adverse event requiring the administration of emergency medications. Proposed new rule N.J.A.C. 13:39-4.20(f) and (g) also requires a pharmacist to retain the standing order in either hard copy or electronic form at the pharmacy practice site or immunization location, and to ensure that a defibrillator is available during the administration of vaccines.

Before administering a vaccine, a pharmacist must screen the patient using CDC criteria for the specific vaccine, and must counsel the patient and/or the patient's representative about contraindications pursuant to proposed N.J.A.C. 13:39-4.20(h). In addition, the pharmacist must obtain the patient or his or her representative's written informed consent to the vaccine administration pursuant to subsections (h) and (i). The informed consent document must be maintained at the pharmacy practice site or in the pharmacist's possession if the immunization location is not a pharmacy practice site.

Proposed N.J.A.C. 13:39-4.20(j) requires the pharmacist to document all immunizations he or she performs. This documentation must include the patient's name and other identifying information, the name of the vaccine administered, as well as the manufacturer, expiration date, lot number, site of administration, and dose, and the name and address of the delegating physician and the administering pharmacist. Pursuant to proposed N.J.A.C. 13:39-4.20(k), the pharmacist must also document and immediately report all clinically significant adverse events to the delegating physician, and to the patient's primary care provider, if the patient has provided this information to the pharmacist as part of the informed

consent document executed prior to the immunization. Proposed N.J.A.C. 13:39-4.20(l) requires the pharmacist to report such events to the appropriate government reporting system within 72 hours of their occurrence.

All documentation required to be maintained by the pharmacist must be kept in either hard copy or electronic form for at least seven years and must be supplied to any physician or health care provider upon receipt of a signed patient release of health information form under proposed N.J.A.C. 13:39-4.20(m).

The State Board of Medical Examiners and the Board of Pharmacy have provided a 60- day comment period for this notice of proposal. Therefore, this notice is excepted from the rulemaking calendar requirement pursuant to *N.J.A.C. 1:30-3.3(a)*5.

Social Impact

The State Board of Medical Examiners believes that proposed new rule N.J.A.C. 13:35-6.26 will have a positive impact upon physicians who wish to participate in patient specific and patient non-specific immunization programs, by ensuring that participating physicians are aware of their responsibilities concerning the supervision they must provide pharmacists administering vaccinations in such programs. The Board of Pharmacy believes that proposed new rule N.J.A.C. 13:39-4.20 will have a positive impact upon pharmacists who wish to participate in patient specific, patient non-specific, and government sponsored immunization programs, by ensuring that participating pharmacists have the requisite training to administer vaccinations safely.

The Boards believe that the proposed new rules may benefit consumers in the State to the extent that they will now have greater access to immunizations, and may have the greatest impact upon those individuals who would not ordinarily seek vaccinations at their physicians' offices. The proposed new rules will allow such individuals the opportunity to obtain immunizations at pharmacy sites throughout the State.

Economic Impact

The State Board of Medical Examiners and the Board of Pharmacy believe that proposed new rules N.J.A.C. 13:35-6.26 and 13:39-4.20 may have an economic impact upon physicians and pharmacists who wish to participate in immunization programs that are either patient specific or patient non-specific, as well as upon pharmacists who wish to participate in immunization programs sponsored by government agencies. Participating physicians may incur administrative costs associated with providing participating pharmacists with the level of supervision mandated in proposed new rule N.J.A.C. 13:35-6.26. Pharmacists may incur administrative costs associated with maintaining required immunization documentation and with submitting such documentation to the Board of Pharmacy for review. In addition, pharmacists who wish to administer immunizations may incur costs associated with obtaining and maintaining the educational qualifications and credentials necessary to obtain Board of Pharmacy approval for participation in such programs.

The Boards also believe that because the proposed new rules will facilitate the administration of vaccines to individuals who would not ordinarily seek vaccinations at their physicians' offices, the proposed new rules may have a beneficial economic impact upon such individuals to the extent that they may experience better overall health, leading to a reduction in their overall healthcare costs.

Federal Standards Statement

A Federal Standards analysis is not required because proposed new rules N.J.A.C. 13:35-6.26 and 13:39-4.20 are governed by N.J.S.A. 45:14-48a(5) and *45:14-63* of the Pharmacy Practice Act. The proposed new rules are not subject to any Federal requirements or standards.

Jobs Impact

The State Board of Medical Examiners and the Board of Pharmacy do not believe that proposed new rules N.J.A.C. 13:35-6.26 and 13:39-4.20 will result in the creation or loss of jobs in the State.

Agriculture Industry Impact

Proposed new rules N.J.A.C. 13:35-6.26 and 13:39-4.20 will have no impact on the agriculture industry in the State.

Regulatory Flexibility Analysis

Currently, the State Board of Medical Examiners licenses approximately 32,000 physicians. The Board of Pharmacy licenses approximately 13,800 pharmacists. If licensees of both Boards are considered "small businesses" within the meaning of the Regulatory Flexibility Act, *N.J.S.A. 52:14B-16* et seq., then the following analysis applies.

Proposed new rule N.J.A.C. 13:35-6.26 will impose various compliance requirements upon physicians who choose to participate in patient specific and patient non-specific immunization programs with licensed pharmacists. Proposed new rule N.J.A.C. 13:39-4.20 will impose various reporting, recordkeeping and compliance requirements upon licensed pharmacists who participate in such immunization programs with licensed physicians, as well as upon pharmacists who choose to participate in patient non-specific immunization programs sponsored by government agencies. These requirements are discussed in the Summary and Economic Impact statements above.

No additional professional services will be needed to comply with the proposed new rules. The costs of compliance with the proposed new rules are discussed in the Economic Impact statement above. The Boards believe that the proposed new rules should be uniformly applied to all physicians and pharmacists who choose to participate in immunization programs in order to ensure the health, safety and welfare of the general public in the provision of immunizations by such licensees. Therefore, no differing compliance requirements for any physicians and/or pharmacists are provided based upon the size of the business.

Smart Growth Impact

The State Board of Medical Examiners and the Board of Pharmacy do not believe that proposed new rules N.J.A.C. 13:35-6.26 and 13:39-4.20 will have any impact upon the achievement of smart growth or upon the implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follow:

13:35-6.26 Procedures for physician ordered immunizations performed by licensed pharmacists

(a) A New Jersey licensed physician may participate in an immunization program with a licensed pharmacist pursuant to *N.J.S.A. 45:14-63* of the Pharmacy Practice Act, provided that the pharmacist is authorized to engage in such activities by the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.20, and provided the pharmacist administers vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, pursuant to:

1. A prescription for the vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific; and/or

2. A physician's standing order for the vaccine, related emergency medications above, and administration instructions that are not patient specific.

(b) A physician shall supervise a licensed pharmacist who is participating in an immunization program implemented pursuant to the physician's standing order. Supervision by the delegating physician shall be deemed adequate if the

delegating physician:

1. Is responsible for formulating or approving a standing order, which shall include compliance with Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/vaccines/pub/pinkbook/downloads/appendices/appdx-full-d.pdf. The standing order shall also include compliance with the American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005), including the use of automated external defibrillators (AED). The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005) are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/vol112/24_suppl/. The order shall also include procedures which shall be followed for the reporting of adverse events. The delegating physician shall annually review the order and the services provided to patients under the order;

2. Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.

3. Is available through direct telecommunication for consultation, assistance, and direction; and

4. Receives annual status reports on the immunization program as administered by the pharmacist.

13:39-4.20 Procedures for physician ordered or government sponsored immunizations performed by pharmacists

(a) The provisions of this section set forth the requirements for licensed pharmacists authorized to administer vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, to eligible patients who are 18 years of age and older, consistent with the requirements of *N.J.S.A. 45:14-63*, under the following circumstances:

1. Pursuant to a prescription by a New Jersey licensed physician for a vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific;

2. In immunization programs implemented pursuant to a New Jersey licensed physician's standing order for the vaccine, related emergency medications, and administration instructions that are not patient specific; and/or

3. In immunization programs sponsored by government agencies that are not patient specific.

(b) In order to administer vaccines and related emergency medications pursuant to this section, a licensed pharmacist shall be pre-approved by the Board to perform such functions. In order to obtain such prior Board approval, a pharmacist shall submit documentation to the Board which establishes that he or she has satisfied the following education and training requirements:

1. Completion of an academic and practical curriculum that includes instruction in Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf. The instruction shall be offered by a provider accredited by the Accreditation Council for Pharmacy Education (ACPE). The curriculum shall include

the following subjects:

i. The Occupational Exposure to Bloodborne Pathogens standard of the Occupational Health and Safety Administration (OSHA), set forth at *29 C.F.R. §1910.1030*, and the New Jersey Public Employees Occupational Safety and Health (PEOSH) Act, set forth at *N.J.S.A. 34:6A-25* et seq., incorporated herein by reference;

ii. CDC Guideline for Infection Control in Health Care Personnel (1998). The CDC Guideline for Infection Control in Health Care Personnel (1998) are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/InfectControl98.pdf;

iii. Basic immunology;

iv. Communicable or vaccine preventable disease epidemiology;

v. Vaccine characteristics, contraindications, monitoring, proper storage and proper handling;

vi. Informed consent;

vii. Pre- and post-vaccine assessment and counseling;

viii. Immunization record management;

ix. Immunization schedules established pursuant to "General Recommendations on Immunization" of the CDC Advisory Committee on Immunization Practices (ACIP) (December 1, 2006), incorporated herein by reference, as amended and supplemented. The ACIP recommendations can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm;

x. Injection techniques;

xi. Emergency responses to adverse events;

xii. Medical waste disposal; and

xiii. Reporting adverse events;

2. Current certification in the American Heart Association Basic Life Support (BLS) protocol or the Red Cross Adult Cardiac Pulmonary Resuscitation (CPR) protocol for health care providers;

3. Current certification in the use of a heart defibrillator; and

4. At least two hours of continuing education in immunizations, consistent with the requirements of *N.J.A.C. 13:39-3A.1*, in each biennial renewal period.

(c) Documentation which establishes that a licensed pharmacist has satisfied the education and training requirements of (b) above shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the documentation shall be maintained in the licensed pharmacist's possession at the immunization location. Such documentation shall be made available for inspection by the Board.

(d) Board approval granted pursuant to this section shall be renewed on a biennial basis. A pharmacist seeking such renewal shall submit documentation which establishes that he or she has satisfied the requirements of (b)2 through 4

above.

(e) A physician's standing order shall specify the procedures that shall be followed for the reporting of adverse events. The licensed pharmacist shall maintain and adhere to a manual of policies and procedures for dealing with acute adverse events. The policies and procedures manual shall require, at a minimum, that the pharmacist immediately notify emergency medical personnel and obtain assistance for the patient when an adverse event requiring the administration of emergency medications occurs. The policies and procedures manual shall be reviewed annually by the licensed pharmacist and such review shall be documented.

(f) Physicians' standing orders shall be maintained in either hard copy or electronic form as provided in (m) below, and shall be available for inspection by the Board at the pharmacy practice site and, if applicable, at the immunization location.

(g) A defibrillator, which shall be maintained in good working order, shall be available during the administration of vaccines, unless the vaccine administration is being done at an emergency government sponsored event. A physician's standing order shall specify that a licensed pharmacist's use of a defibrillator shall be consistent with American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. The AHA guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005), including use of automated external defibrillators (AED), are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/vol112/24_suppl/.

(h) Before administration of a vaccine, the licensed pharmacist shall:

1. Screen the patient using CDC established criteria for each specific vaccine to be administered;

2. Counsel the patient and/or the patient's representative about contraindications, proper care of the injection site, and instructions to contact a physician or emergency care facility in the event of any adverse reaction;

3. Inform the patient and/or the patient's representative in writing, in specific and readily understood terms, about the risks and benefits of the vaccine and provide the patient with a vaccine information sheet published by the CDC; and

4. Obtain a signed informed consent form, which complies with the requirements of (i) below, from the patient or the patient's representative which shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the signed informed consent forms shall be maintained in the licensed pharmacist's possession at the immunization location. The signed informed consent forms shall be maintained in either hard copy or electronic form as provided in (m) below.

(i) The informed consent form provided by a licensed pharmacist to a patient shall contain a check-off box which authorizes the pharmacist to send copies of the patient's vaccine documentation to the patient's primary care provider, and another check-off box which prohibits the pharmacist from sending copies of the patient's vaccine documentation to the patient's primary care provider. The informed consent form shall specify that a patient's failure to select one of the two check-off boxes shall result in the patient's vaccine documentation being sent to the patient's primary care provider, if identified.

(j) The licensed pharmacist shall document all immunizations he or she performs and such documentation shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the documentation shall be maintained in the licensed pharmacist's possession at the immunization location, and then transferred to the pharmacy practice site. Such documentation shall be retained in either hard copy or electronic form, consistent with (m) below, and shall be made available for inspection by the Board. Such documentation shall include:

1. The patient's name, address, telephone number, date of birth, allergies and gender;

2. The vaccine administered, the manufacturer, expiration date, lot number, site of administration, and dose administered;

3. The date of original order and the date of administration(s);

4. The name and address of the delegating physician, and the name and address of the licensed pharmacist administering the dose, and the immunization location, if different from the pharmacy practice site; and

5. The name and address of the patient's primary care provider, if provided.

(k) The licensed pharmacist shall document in detail and immediately report all clinically significant adverse events to the delegating physician, and to the primary care provider, if identified and if authorized on the informed consent form consistent with (i) above. The licensed pharmacist shall, within 72 hours, report such events to the appropriate government reporting system.

(l) The licensed pharmacist shall provide a copy of all patient related documentation and a copy of the signed informed consent form to each patient receiving an immunization, or to the patient's representative, to the patient's primary care provider, if provided and if authorized on the informed consent form consistent with (i) above, and if applicable, to the appropriate government reporting system.

(m) All documentation and records required to be maintained by this section shall be maintained in either hard copy or electronic form for a period of not less than seven years and shall be supplied to any physician or health care provider upon receipt of a signed patient release of health information form. All records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. The oldest six years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure. Patient records shall be kept confidential.

(n) In the case of immunization programs implemented pursuant to a physician's standing order, a licensed pharmacist shall be supervised by the delegating physician. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

1. Is responsible for formulating or approving a standing order, periodically reviewing the order and the services provided to patients under the order;

2. Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.

3. Is available through direct telecommunication for consultation, assistance, and direction; and

4. Receives annual status reports on the immunization program as administered by the pharmacist.